K001706

AUG 1 6 2000

WRIGHT
MEDICAL TECHNOLOGY, INC.
5677 AIRLINE ROAD
ARLINGTON, TN 38002
901-867-9971

510K Summary

Company: Wright Medical Technology, Inc.
5677 Airline Road
Arlington, TN 38002
Contact Person: Lynne Witkowski
Date: June 2, 2000
Trade Name: WMT Modular Shoulder System
Common Name: Shoulder prosthesis
Predicate Device: 3M Modular Shoulder System

Description/Intended Use:
The WMT Modular Shoulder System includes humeral heads in five sizes. A regular length and long length humeral stem are available in identical diameters. Both humeral stems have four proximal flanges: one lateral, two anterior/posterior and one medial. The lateral flange has three suture holes and the anterior/posterior fins have one suture hole each. Both the regular and long stems are manufactured from titanium alloy (ASTM F 136). The heads are manufactured from cobalt chrome (ASTM F 1537, warm worked or ASTM F 799).

Intended Use:
The WMT Modular Shoulder System, humeral head and stem, is intended for use as a total or hemi-arthroplasty. When used for total shoulder arthroplasty, the subject components are recommended for use with 3M Neer II™ Shoulder (K895226, SE 11/3/89) compatible glenoid components.

Indications for Use:

- Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
- Rheumatoid arthritis;
- Revision where other devices or treatments have failed;
- Correction of functional deformity;
- Treatment of acute fracture of the humeral head unmanageable using other treatment methods; and
- Cuff tear arthroplasty.

Hemi-shoulder replacement is also indicated for:

- Ununited humeral head fractures; and
- Avascular necrosis of the humeral head.

The humeral stem may be implanted by press-fit or cement fixation.

Testing Summary:
The WMT Modular Shoulder System was declared substantially equivalent to the predicate device. Mechanical test data demonstrated that the material and subject device design meet the strength requirements of the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 6 2000

Ms. Lynne Witkowski
Regulatory Affairs Associate
Wright Medical Technology, Inc.
5677 Airline Road
Arlington, Tennessee 38002

Re: K001706
Trade Name: WMT Modular Shoulder System
Regulatory Class: II
Product Codes: KWS and HSD
Dated: May 31, 2000
Received: June 5, 2000

Dear Ms. Witkowski:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known) K001706

Device Name WMT Modular Shoulder System

Indications for Use

Intended Use

The WMT Modular Shoulder System, humeral head and stem, is intended to be used for total or hemi-arthroplasty. When used for total shoulder arthroplasty, the subject components are to be used with existing 3M shoulder glenoid components cleared in K920362 or with 3M Neer II™ Shoulder (K895226, SE 11/3/89) ~~compatible glenoid~~ components.

Indications for Use:

- Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
- Rheumatoid arthritis;
- Revision where other devices or treatments ~~have failed~~;
- Correction of functional deformity;
- Treatment of acute fracture of the humeral ~~head unmanageable~~ using other treatment methods; and
- Cuff tear arthroplasty.

Hemi-shoulder replacement is also indicated for:

- Ununited humeral head fractures; and
- Avascular necrosis of the humeral head.

The humeral stem may be implanted by press-fit or cement fixation.

PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Kochner

(Division Sign-O
Division of Gene estorative Devices

510(k) Number K001706

Prescription Use ✓ (per 21 CFR 801.109) OR Over-The Counter Use ____